Remarks/Arguments

The specification has been amended to add an Abstract. The text of the abstract is taken from the Background of the Invention, found on page 1 of the specification and does not add new matter.

Claims 34-60 remain in this application.

Claim Rejections – 35 U.S.C. § 101

Section 3a: Claims 48-60 are rejected under 35 U.S.C. § 101 as allegedly directed to non-statutory subject matter. It is specifically stated that 'a host cell' encompasses the cell as it occurs in nature. Applicant's representative disagrees for the following reason.

The claims of an application must be read in light of all of their limitations. The Examiner's current reading of the claim does not take into account the additional limitations requiring the cells to be 'transfected or transduced' with a vector, wherein the vector is described in prior claims. Transfection or transduction requires the intervention of a person to introduce a nucleic acid sequence into a host cell, in other words, the 'hand of man.' No naturally occurring host cell would be transfected or transduced with a vector, as described and claimed, without the intervention of a human. Therefore, it is respectfully submitted that these claims are in fact drawn to statutory subject matter and withdrawal of this portion of the rejection is respectfully requested.

Section 4a: Claims 34-59 are rejected under 35 U.S.C. § 101 as allegedly not supported by a specific or substantial asserted utility or a well established utility. Applicant's representative disagrees for the following reason.

The specification provides a nucleic acid sequence that is similar in sequence and general structure to IL-1 receptor (IL-1R) encoding nucleic acids. In addition, the nucleic acid sequence has been mapped to the chromosome 11p15.5 region, wherein it is well known that this region is subject to loss of heterozygosity (LOH) in a number of diseases including Wilms' tumor, rhabdomyosarcoma, breast cancer, non-small cell lung carcinoma (NSCLC), among others as described in the specification as filed, and therefore, the present nucleic acid can be used as a novel marker sequence to determine LOH for diagnostic and prognostic uses.

What is sufficient for a specific assertion of utility is defined in M.P.E.P. § 2107.01. In the case of a gene probe, it is not sufficient if the target is not known. However, the M.P.E.P. instructs Examiners that sufficient utility has been shown when the target is known, or in other words, when the genomic locus is known.[1] This is precisely the case here. Not only is the location of the SIGIRR genetic locus

[1] M.P.E.P. § 2107.01 states: A "specific utility" is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention. ... a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be specific in the

known (*i.e.*, the SIGIRR genomic locus is at 11p15.5), but it also falls squarely in the midst of a number of genetic disorders discussed in the specification and in various journal references (see, *e.g.*, Deng et. al. (1996) Science, vol. 274, 2057). Many of these disorders manifest themselves after undergoing substantial genetic rearrangements such as LOH, and these rearrangements are readily detectable using SIGIRR nucleic acids in diagnostic assays either on carrier DNA or for prenatal diagnosis of fetus DNA. Therefore, in view of the standard set forth for specific utility by the Office and the fact that the present nucleic acid has a specifically defined genetic locus in the midst of an important chromosomal location associated with numerous disorders associated with LOH and wherein the claimed sequences can be used as gene probes in this region, it is respectfully submitted that the presently claimed nucleic acid sequences have specific utility.

The Office has defined a substantial utility as "one that is likely to benefit the public. More particularly, a "substantial utility" defines a "real world" use, such as ... [a]n assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring." M.P.E.P. section 2107.01. It has been asserted that SIGIRR nucleic acids can be used to detect LOH in individuals, and these LOH events are associated with diseases. These facts match the criteria set forth by the Office. Thus, in view of the importance of the above asserted utility of diagnosis and prognosis of genetic disorders, and in view of the standards promulgated by the Office, it cannot be held that the presently claimed invention lacks substantial utility and this part of the rejection should be withdrawn.

Furthermore, recent decisions by the Federal Circuit have held that an applicant need recite only one objective utility in order to satisfy the requirements under 35 U.S.C. 101. Importantly, the presence of additional asserted utilities, whether deemed by the Office credible or not, does not affect the sufficiency of a particular utility under the rules. Indeed, M.P.E.P. section 2107.02 states: It is common and sensible for an applicant to identify several specific utilities for an invention, particularly where the invention is a product ... [h]owever, regardless of the category of invention that is claimed ... an applicant need only make one credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C. 101 and 35 U.S.C. 112; additional statements of utility, even if not "credible," do not render the claimed invention lacking in utility. See, *e.g.*, *Raytheon v. Roper*, 724 F.2d 951, 958, 220 USPQ 592, 598 (Fed. Cir. 1983), cert. denied, 469 U.S. 835 (1984) ("When a properly claimed invention meets at least one stated objective, utility under 35 U.S.C. 101 is clearly shown.") ... *In re Gottlieb*, 328 F.2d

---

absence of a disclosure of a specific DNA target. A general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed. Knapp v. Anderson, 477 F.2d 588, 177 USPQ 688 (CCPA 1973) [emphasis added].

1016, 1019, 140 USPQ 665, 668 (CCPA 1964) ("Having found that the [product] is useful for some purpose, it becomes unnecessary to decide whether it is in fact useful for the other purposes 'indicated' in the specification as possibly useful" [emphasis added]). Thus, as is stated in the M.P.E.P., "if applicant makes one credible assertion of utility, utility for the claimed invention as a whole is established."

Accordingly, the asserted utilities for the claimed invention are specific, substantial, and well established and therefore satisfy the requirements for patentability. It is respectfully requested that this part of the rejection be withdrawn.

Section 4b: Claims 34-60 are rejected under 35 U.S.C. §112 first paragraph for allegedly lacking a sufficient teaching to make and use the invention in view of the above described utility rejection, *i.e.*, one cannot teach how to use that which has no use. It is respectfully submitted that the above made arguments have overcome the utility rejection and accordingly, the rejection for failure to teach how to use the invention has been mooted.

However, it is also alleged that the claims, in particular those that recite nucleic acids having a percentage identity with the sequences of SEQ ID NO:1 or that encode a polypeptide of SEQ ID NO:2 "...broadly encompass a significant number of inoperative species." Applicant's representative respectfully dissents.

The Office Action appears to have made the assumption that the only useful purpose for nucleic acids is to encode polypeptides, and that the polypeptides must be an IL-1R-like molecule that is functional. This is not correct. The specification provides utility for the nucleic acids that include uses as diagnostic or prognostic markers. These sequences do not need to be of a sequence that encodes a particular polypeptide having a particular function, rather, the nucleic acid need only hybridize to the proper genomic locus. This hybridization is well known to occur even when sequences have divergent sequences on the order of those presently claimed.

Thus, it is respectfully submitted that this rejection is in error and withdrawal is requested.

Section 5: Claims 3-4 and 19-20 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for particularly point out and distinctly claim that which the applicant regards as the invention.[2] The Office Action then notes in Section 5a that Claim 59 recites the acronym TIGIRR, which is improper, as it is unclear what this acronym stands for. Applicant is advised to recite the full name for TIGIRR.

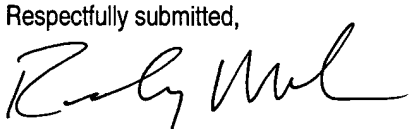
[2] As claims 3-4 and 19-20 have been cancelled, it is assumed that the Office Action has rejected all claims that recite 'TIGIRR' for the reasons cited.

Applicant's representative submits that the acronym TIGIRR is in fact the proper name for the subject nucleic acids and polypeptides. Applicant is entitled to name any novel sequence he sees fit, and that includes using a name that arose from an acronym. Since there is no other sequence known to Applicant's representative with the same name as TIGIRR, and since the name TIGIRR has been accepted by the scientific community as properly denoting the sequences shown in SEQ ID Nos:1 and 2 (see, *e.g.*, Thomassen et al., Cytokine, vol. 11, No. 6., 1999, pp389-399, provided by the Examiner attached to the pending Office Action), it is respectfully submitted that this rejection is in error. Withdrawal of this portion of the rejection is requested.

CONCLUSION

Applicant respectfully submits that the application is in condition for allowance, and respectfully requests issuance of a notice of allowance. The Examiner is encouraged to telephone the undersigned in order to resolve any outstanding issues in the present application and to facilitate its prosecution.

Respectfully submitted,



Randolph N. Mohr, Ph.D.
Registration No. 45,590
DIRECT DIAL (805) 447-8949

Please Send Future Correspondence To:

Immunex Corporation
Law Department
51 University Street
Seattle, Washington 98101